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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,845	PROGULSKE-FOX ET AL.	
	Examiner	Art Unit	
	AMBER D. STEELE	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/26/10, 12/4/09, 9/11/09, and 7/23/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *6 and 11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *November 15, 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-17 were originally filed on November 15, 2001.

The amendment to the claims received on July 18, 2007 amended claims 4, 10, and 17.

The amendment to the claims received on July 18, 2008 amended claims 2-3.

The amendment to the claims received on July 23, 2009 amended claims 1, 6, 7, 10, 11, 13, and 15.

The amendment to the claims received on September 11, 2009 amended claims 1, 2, 6-9, 11, 13, 15, and 17 and added new claims 18 and 19.

Claims 1-19 are currently pending.

Claims 1-5, 7-10, 18, and 19 are under consideration.

Election/Restrictions

2. Applicant's election with traverse of Group I in the reply filed on December 4, 2009 and April 26, 2010 is acknowledged. The traversal is on the ground(s) that a "need for a restriction has not developed in this case", that the "examiner has clearly searched, examined and carefully considered all of the claims", and that Ebersole et al. does not break Unity of Invention. This is not found persuasive because the claim amendments received on September 11, 2009 necessitated the restriction requirement due to additional method steps and limitations added to the claims (i.e. additional method steps and limitations added to the claims changed the claim scope therefore "the same exact subject matter" is not present). In addition, it was noted in the previous Office action clearly stated that a search of the claims was not possible due to the indefinite nature of the claim scope (see Office action mailed on April 23, 2009, section 19).

Furthermore, Ebersole et al. teach methods comprising collecting serum comprising antibodies from patients infected with *A. actinomycetemcomitans*, growing *A. actinomycetemcomitans* in culture, performing ELISAs, and performing adsorption studies (please refer to the entire reference particularly Methods section; i.e. the common technical feature as claimed). Additionally, Bickel et al. WO 98/30910 teach methods comprising (a) obtaining an antibody sample from a host infected with a microbe or pathogen, (b) incubating the antibody sample with cells to form antibody-antigen complexes, (c) removing antibodies that do not form complexes, and (d) screening the subtractive antibody sample for binding to cells wherein polynucleotides can also be isolated (please refer to the entire specification particularly Figure 1; pages 4-7; i.e. additional reference that breaks unity of invention).

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 6 and 11-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 4, 2009 and April 26, 2010.

Priority

4. The instant application, Serial No. 09/980,845, filed 4/8/2002, states that it is the national stage of PCT/US00/21340, international filing date 8/4/2000; which claims benefit of U.S. Provisional Application 60/147,551, filed 8/6/1999.

Withdrawn Objections

5. The objection to the drawings regarding the lack of description of Figure 6 is withdrawn in view of the amendment received on July 23, 2009.

6. The objection to the disclosure regarding the first line of the specification is withdrawn in view of the amendment received on July 23, 2009.

New Objections

Claim Objections

7. Claim 7 is objected to because of the following informalities: line 3 reads "with, with". Appropriate correction is required.

Withdrawn Rejections

8. The rejection of claims 8-9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the claim amendments received on September 11, 2009.

9. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the claim amendments received on September 11, 2009.

10. The rejection of claim 10 regarding the lack of antecedent basis is withdrawn in view of the claim amendments received on July 23, 2009.

New Rejections

Claim Rejections – 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1-5, 7-10, 18, and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. See In re Bilski, 88 USPQ2d 1385 (Fed. Cir. 2008) which held that: a process claim is not drawn to patent-eligible subject matter under 35 U.S.C. §101 if it recites a fundamental principle, and if effect of allowing claim would be to allow patentee to preempt substantially all uses of that fundamental principle. However, if a process claim that recites fundamental principle is tailored narrowly enough to encompass only a particular application of that principle, and thus is patent eligible under 35 U.S.C. §101, if claimed process is tied to particular machine or apparatus, or if it transforms particular article into different state or thing (emphasis added); although future developments in technology and sciences may present difficult challenges to this "machine-or-transformation" test, at present it is the governing test for determining patent eligibility of a process under Section 101. Process claims that recites fundamental principle, and that otherwise fails "machine-or-transformation" test for whether such claim is drawn to patentable subject matter under 35 U.S.C. §101, is not rendered patent eligible by mere field-of-use limitations; another corollary to machine-or-transformation test is that recitation of specific machine or particular transformation of specific article does not transform unpatentable principle into patentable process if recited machine or transformation constitutes mere "insignificant post-solution activity." Thus, claims that recite physical steps, but neither recites particular machine or apparatus, nor transforms particular

article into different state or thing, is not drawn to patentable subject matter, whereas claim that purportedly lacks any physical steps, but is still tied to machine or achieves eligible transformation, satisfies requirements of Section 101.

The presently claimed method is drawn to a screening method which is not tied to a particular machine or apparatus and does not transform a particular article into a different state or thing. The presently claimed method analyzes a natural phenomenon (i.e. analysis of a polynucleotide of a microbe or pathogen that is expressed *in vivo*).

Claim Rejections – 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-5, 7-10, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection. While the specification teaches obtaining a sera sample from one or more hosts infected with the microbe or pathogen (see pages 3, 4, 5, 8, etc.), the specification does not teach "obtaining an antibody sample from one or more hosts infected with the microbe or pathogen" (see present method steps a).

15. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a screening method to isolate clones, the specification

does not reasonably provide enablement for a method to isolate a vaccine or diagnostic target. The specification does not enable a person skilled in the art to make and use the invention commensurate in scope with the claim. This is a **scope of enablement** rejection.

There are many factors to consider when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any experimentation is "undue". These factors include, but are not limited to:

1. The breadth of the claims;
2. The nature of the invention;
3. The state of the prior art;
4. The level of skill in the art;
5. The level of predictability in the art;
6. The amount of direction provided by the inventor;
7. The presence or absence of working examples;
8. The quantity of experimentation necessary needed to make or use the invention

based on the disclosure.

See *In re Wands* USPQ 2d 1400 (CAFC 1988):

The breadth of the claims and the nature of the invention:

The claimed invention is drawn to methods comprising (a) obtaining an antibody sample from one or more hosts infected with the microbe or pathogen, (b) adsorbing the antibody sample with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*, (c) isolating unadsorbed antibodies; and (d) probing an expression library of clones of the microbe or pathogen with the unadsorbed antibodies of (c) and isolating clones from the expression

library to which the unadsorbed antibodies bind and variations thereof wherein a vaccine or diagnostic target is isolated. Accordingly, the claims encompass any host, any microbe, any pathogen, any antigen, any antibody, etc. Intended use of the final product as a vaccine or diagnostic target further exacerbates the lack of enablement since the specification does not disclose a single species of vaccine or diagnostic target. Accordingly, the claim scope is unduly broad with respect to encompassed host, microbe, pathogen, antibody, antigen, vaccine, and diagnostic target.

The state of the prior art and the level of predictability in the art:

Despite years of research to develop potential vaccines and vaccine candidates for various bacteria (i.e. bacteria involved in periodontitis, *Actinobacillus pleuropneumoniae*), a vaccine for bacterial infection (i.e. bacteria involved in periodontitis, *Actinobacillus pleuropneumoniae*) has not been found. Many factors including etiology and pathogenic mechanisms involved in infection, necessity to elicit various immune responses (i.e. cell-mediated, humoral, mucosal) for a robust vaccine, various serotypes and strains which cause infection in different hosts, multifactoral and polymicrobial cause of disease, etc. are involved in determining vaccine candidates. Furthermore, various experiments are necessary to discover vaccine and diagnostic candidates without a guarantee for success in future vaccine or diagnostic development. For example, studies in animal models may not directly correlate to humans and a multi-antigenic vaccine may be necessary (i.e. discovery of multiple antigens necessary). Issues with subunit (single antigen or multi-antigenic) vaccines include low level immunogenicity, contamination with other virulence factors, limited or partial protection, necessity to discover highly immunogenic antigens with a broad protection, utilization of adjuvants (i.e. additional

research to discover proper vaccine formulation), selection of appropriate immunization route (e.g. additional research to discover proper immunization route, dosage, necessity for boosters, etc.). See Sharma et al., Expert Rev. Vaccines 6(4): 579-590, 2007 and Ramjeet et al., Animal Health Research Reviews, 9(1): 25-45, 2008. In addition, the various serotypes and strains involved in infection create an issue for creating a reliable diagnostic tool as well. Therefore, the level of predictability in the art is dependent on many factors. While development of vaccines and diagnostics is important, the state of the art requires vast amounts of data including discovery of single or multiple antigens and definitive experiments to ensure that the antigen(s) are sufficiently immunogenic; various animal studies using various animal models; and phase 0, I, II, III, and IV trials.

The level of skill in the art:

The level of skill would be high, most likely at the Ph.D. level.

The amount of direction provided by the inventor and the existence of working examples:

There are no specific examples directed to the presently claimed invention of screening for vaccines or diagnostic targets; nor is there any guidance as to how to specifically utilize the final products of the methods to obtain a vaccine or diagnostic target which is within the scope of the presently claimed invention. The general teachings in the specification and the method of identifying polynucleotide sequences of SEQ ID NO: 1-8 (see Example 3) which encode antigens of *Actinobacillus actinomycetemcomitans* (please refer to pages 7 and 15-16 and Examples 1-3) do not provide any information regarding vaccine development or use as diagnostic targets.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure:

In light of the unpredictability surrounding the claimed subject matter, the undue breadth of the claimed invention's intended use, and the lack of adequate guidance, one wishing to practice the presently claimed invention would be unable to do so without engaging in undue experimentation. One wishing to practice the presently claimed invention would have to produce additional data utilizing various experiments including phase 0, I, II, III, and IV clinical trials for vaccine development and various quality control experiments for use of the final product of the screening method as a "diagnostic target".

Claim Rejections – 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-5, 7, 8, 10, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bickel et al. WO 98/30910 published July 16, 1998 (provided by applicants in the IDS).

For present claims 1-5, 7, 8, 10, 18, and 19, Bickel et al. teach methods comprising (a) obtaining an antibody sample from an immunized host (i.e. "infected" with a microbe or pathogen, immunized with cells or cell fractions) including rabbits, (b) contacting the antibody sample with a first cell population to form antibody-antigen complexes, (c) isolating antibodies which do not form complexes (i.e. immunodepletion, subtracted), (d) contacting the antibodies of method step (c) with clones (e.g. cells, proteins, polynucleotides, etc.) of a second cell

population, (e) isolating polynucleotides, and (f) sequencing the polynucleotides (please refer to the entire specification particularly the abstract; Figure 1; pages 2-15, 18, 23). In addition, Bickel et al. teach that the first and second cell populations and cells or cell fractions can be any type of tissue including normal tissue, metastatic malignant tissue, non-metastatic malignant tissue, cultured cells, immortalized cultured cells, blood cells, prokaryotic cells, bacteria, eukaryotic cells, fungal, insect, plant, vertebrate, mammalian, human, etc. (please refer to the entire specification particularly pages 5, 6, 7, 10).

Therefore, the teachings of Bickel et al. anticipate the presently claimed method.

Claim Rejections – 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 1-5, 7-10, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bickel et al. WO 98/30910 published July 16, 1998 (provided by applicants in the IDS) and Suk et al., *Borrelia burgdorferi* genes selectively expressed in the infected host, PNAS, 92: 4269-4273, 1995 (provided by applicants in the IDS).

For present claims 1-5, 7, 8, 10, 18, and 19, Bickel et al. teach methods comprising (a) obtaining an antibody sample from an immunized host (i.e. "infected" with a microbe or pathogen) including rabbits, (b) contacting the antibody sample with a second cell population to form antibody-antigen complexes, (c) isolating antibodies which do not form complexes (i.e. immunodepletion, subtracted), (d) contacting the antibodies of method step (c) with clones (e.g.

cells, proteins, polynucleotides, etc.), (e) isolating polynucleotides, and (f) sequenceing the polynucleotides (please refer to the entire specification particularly the abstract; Figure 1; pages 2-15, 18, 23). In addition, Bickel et al. teach that the first and second cell populations can be any type of tissue including normal tissue, metastatic malignant tissue, non-metastatic malignant tissue, cultured cells, immortalized cultured cells, blood cells, prokaryotic cells, bacteria, eukaryotic cells, fungal, insect, plant, vertebrate, mammalian, human, etc. (please refer to the entire specification particularly pages 5, 6, 7, 10).

However, Bickel et al. does not specifically teach *Borrelia*.

For present claim 9, Suk et al. teach methods of immunological screening to select microbial genes expressed only in the host by differential screening of *Borrelia burgdorferi* (please refer to the entire specification particularly the abstract).

The claims would have been obvious because the substitution of one known element (i.e. genus of bacteria taught by Bickel et al.) for another (i.e. species of *Borrelia burgdorferi* taught by Suk et al.) would have yielded predictable results (i.e. ability to screen for gene specific for *Borrelia burgdorferi*) to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Maintained Rejections

Claim Rejections - 35 USC § 112

20. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claims 1-5, 7-10, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 USC 112, first paragraph "Written Description" requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a **written description** rejection.

The method of claims 1, 18, and 19 are drawn to a method comprising (a) obtaining an antibody sample from one or more hosts infected with the microbe or pathogen, (b) adsorbing the antibody sample with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*, (c) isolating unadsorbed antibodies; and (d) probing an expression library of clones of the microbe or pathogen with the unadsorbed antibodies of (c) and isolating clones from the expression library to which the unadsorbed antibodies bind and variations thereof. The invention as claimed encompasses all known antibodies, antigens, microbes, pathogens, etc. and all potential antibodies, antigens, microbes, pathogens, etc. since virtually any antibodies, antigens, microbes, pathogens, etc. can be utilized in a screening assay. The claimed invention does not include any structural information regarding the antibodies or antigens. Furthermore, the necessity to isolate a "vaccine" or "diagnostic target" (see claims 18 and 19) further exacerbates the lack of written description since the specification fails to describe a single species of "vaccine" or "diagnostic target".

The specification teaches a method of identifying polynucleotide sequences of SEQ ID NO: 1-8 (see Example 3) which encode antigens of *Actinobacillus actinomycetemcomitans* (please refer to pages 7 and 15-16 and Examples 1-3). Therefore, one skilled in the relevant art would not reasonably conclude that the Applicants had possession of the invention as claimed.

See Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was *in possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116.).

With the exception of SEQ ID NOs: 1-8 and *Actinobacillus actinomycetemcomitans* antigens as disclosed by the specification, the skilled artisan cannot envision the method of claims 1-5, 7-10, 18, and 19. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class wherein the specification provided only the bovine sequence.

The written description requirement for claims drawn to or utilizing antibodies and antigens require that either the antibody or antigen is taught due to the nature of antigen-antibody binding and the required specificity for useful products. For example, disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a

public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (holding there is a lack of written descriptive support for an antibody defined by its binding affinity to an antigen that itself was not adequately described). In addition, the limitations in claims 4 and 10 regarding the animals and the limitations in claims 8-9 regarding the pathogens equate to a laundry list of potential animals and pathogens. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species).

Additionally, Cf. University of Rochester v G.D. Searle & Co., Inc., Monsanto Company, Pharmacia Corporation, and Pfizer Inc., No. 03-1304, 2004 WL 260813 (Fed. Cir., Feb. 13, 2004) held that: *Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.*

Moreover, Ariad Pharmaceuticals Inc. v. Eli Lilly & Co., 94 USPQ2d 1161 (Fed. Cir. 2010) held that: The written description requirement ensures that, if chemical or biotechnology patent claims genus by its function or result, specification recites sufficient materials to

accomplish that function; without written description requirement, claims that merely recite description of problem to be solved while claiming all solutions to it would cover any compound later actually invented and determined to fall within claim's functional boundaries, leaving it to pharmaceutical industry to complete unfinished invention. Written description doctrine must be applied even though it may disadvantage inventors to extent that basic research cannot be patented, since patent law has always been directed to "useful Arts," meaning inventions with practical use, since inventors may not have resources or inclination to work out practical implications of basic research into scientific principles and mechanisms of action, and since requiring written description of invention properly limits patent protection to those who actually conceive of complete and final invention with all its claimed limitations, and disclose fruits of that effort to public; although fact that research hypotheses do not qualify for patent protection may result in some loss of incentive, claims to research plans also impose costs on "downstream" research, discouraging later invention, and written description doctrine sets correct balance by giving incentive to actual invention rather than attempts to "preempt the future before it has arrived." Much research relates to basic research, including research into scientific principles and mechanisms of action, *see, e.g.*, *Rochester*, 358 F.3d 916, and inventors may not have the resources or inclination to work out the practical implications of all such research, *i.e.*, finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention. Patents are not awarded for theories, no matter how groundbreaking or necessary to the later patentable inventions of others. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id.* at 930 n.10 (quoting *Brenner*, 383 U.S. at 536). Requiring a

written description of the invention limits patent protection to those who actually perform the difficult work of "invention"—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public.

Arguments and Response

22. Applicants' arguments directed to the rejection under 35 USC 112, first paragraph (written description), for claims 1-5, 7-10, 18, and 19 were considered but are not persuasive for the following reasons.

Applicants contend that one of skill in the art would recognize that applicants were in possession of a method of isolating a polynucleotide as presently claimed due to the general disclosure in the specification.

Applicants' arguments are not convincing since the presently claimed method lacks written description. Applicants have not adequately described the genus of reagents necessary to perform the presently claimed method (e.g. antibodies that bind only antigens expressed *in vivo*, etc. for any microbe or pathogen). The specification only teaches reagents for use in a method of screening and subsequently isolating polynucleotides from *Actinobacillus actinomycetemcomitans*.

23. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

24. Claims 1-5, 7-10, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the

scope of the presently claimed invention. The method of independent claims 1, 18, and 19 has four method steps (i.e. a, b, c, and d). However, other potential method steps are present and it is not clear if these steps are required or not. After method steps d, the statements "wherein a polynucleotide…is isolated" (claim 1), "wherein a vaccine target...is isolated" (claim 18), and "wherein a diagnostic target…is isolated" (claim 19) are present. However, it is not clear if this is a separate method step (i.e. required method step for a proper nexus between the preamble and the method steps). In addition, method step a has statements that appear to be "product-by-process" limitations regarding the reagents utilized (i.e. cell or cellular extracts of the microbe or pathogen "that have been grown *in vitro*"). Therefore, it is not clear if method steps regarding production of the cell or cellular extracts are required by the claims or not. However, applicant is cautioned that no new matter may be added.

Arguments and Response

25. Applicants' arguments directed to the rejection under 35 USC 112, second paragraph (indefinite), for claims 1-5, 7-10, 18, and 19 were considered but are not persuasive for the following reasons.

Applicants contend that the amendments to the claims negate the rejection and that after reading the specification one of skill in the art would understand the scope of the claims.

Applicants' arguments are not convincing since the claim amendments have negated only some of the indefinite claim language (see the modified rejection above). In addition, except for clear definitions of terms in the specification, limitations from the specification can not be read into the claims. Furthermore, "clones" (e.g. cell, bacteria, etc.) is not synonymous with "polynucleotide".

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 1-5, 7-10, 18, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 12/327,056. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions as claimed in U.S. application 12/327,056 are drawn to methods of isolating a polynucleotide from a microbe utilizing antibodies and antigens.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Arguments and Response

28. Applicants' arguments directed to the rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 12/327,056 for claims 1-5, 7-10, 18, and 19 were considered but are not persuasive for the following reasons.

Applicants request that the rejection be held in abeyance.

Applicants' arguments are not convincing since the claimed invention of 12/327,056 renders obvious the method of the instant claims. In addition, while a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated, the present is a rejection and will not be held in abeyance (see MPEP § 714.02).

Conclusion

29. The full-length sequence of SEQ ID NO: 13 with 100% identity is free of the prior art. Therefore, closed claim language regarding SEQ ID NO: 13 or claim language requiring to full-length sequence of SEQ ID NO: 13 (i.e. a polynucleotide comprising **the** sequence of SEQ ID NO: 13; emphasis added; claim language would allow for 5' and 3' additions) would be allowable.

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 99/15897.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639